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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,483

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Mitsuru Hasegawa

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KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

BOSWORTH, KAMI A

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

02/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,483	Applicant(s) HASEGAWA, MITSURU	
	Examiner KAMI A. BOSWORTH	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/20/2010 has been entered.

Claim Objections

2. Claim 9 is objected to because of the following informalities: Upon further review, it appears that claim 9 should recite " $A + B + C > D$ " as this is supported by the specification and amended Figure 5. For the sake of examination, this claim will be prosecuted both ways (once wherein $A + B + C < D$ and once wherein $A + B + C > D$). Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

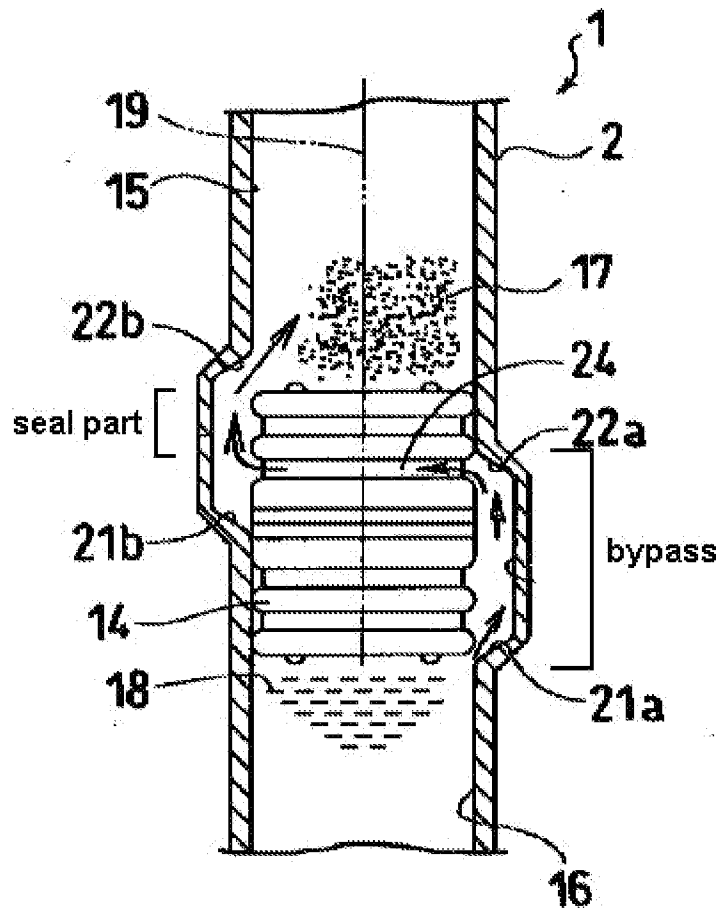
4. Claims 1 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Tanaka et al. (PG PUB 2004/0236273).

5. Re claim 1, Tanaka et al. disclose a pre-filled syringe 1 (Fig 1) which comprises a barrel 2 (Fig 1) having a tip 3 (Fig 1) in which a nozzle (the portion of nozzle member 6 to which the needle is attached, Para 41) (Fig 1) is provided and an open base end 4 (Fig 1) and having an axis 19 (Fig 1) extending from said tip to said open base end, an intermediate gasket 14 (Fig 1,9) liquid-tightly partitioning an inside of the barrel into a front chamber 15 (Fig 1) and a rear chamber 16 (Fig 1) (Para 16,20), a plunger gasket 13 (Fig 1) located in a base end side of the intermediate gasket and sealing the inside of the barrel (Para 20), and a plunger rod 7 (Fig 1) connected to a base end of the plunger gasket (Para 20, Fig 1), and in which in a tip side of the barrel relative to the intermediate gasket there is formed a bypass 20a (Fig 1,9) protruding outwardly in a radial direction (as seen in Fig 1,9), wherein the intermediate gasket includes a seal part (portion of gasket toward the tip side of channel 24, as seen in Fig 9 and Fig A below) contacting an inner wall of the barrel and liquid-tightly partitioning the front chamber and the rear chamber (Para 16,20,23), and a bypass communication passage 24 (Fig 9) providing communication between the front chamber and the rear chamber in cooperation with the bypass (Para 23), and wherein an axial length of the intermediate gasket parallel to the axis of the barrel is longer than an axial length of the bypass parallel to the axis of the barrel, and when the axial length of the bypass is a1 and an

axial effective length of the seal part is b_1 , $a_1 > b_1$ (best seen in Fig A below).

Fig A

(annotated Fig 9 of Tanaka et al.)



6. Re claim 9 (as currently written), Tanaka et al. disclose that if an axial length of a tip gasket 12 (Fig 1) parallel to the axis of the barrel is A, an axial length of the intermediate gasket 14 (Fig 1) parallel to the axis of the barrel is B, an axial length of the plunger gasket 13 (Fig 1) parallel to the axis of the barrel is C and a length from an inner wall tip of a nozzle member to an inner wall base end 21 (Fig 1) of the bypass is

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D, $A + B + C < D$ (as seen in Fig 1, the total combined axial length of all the gaskets is significantly less than the length from the nozzle to the base end of the bypass).

7. Re claim 10, Tanaka et al. disclose that the barrel additionally comprises a tip gasket 12 (Fig 1), and the front chamber is formed between the tip gasket and the intermediate gasket (as seen in Fig 1; Para 42).

8. Re claim 11, Tanaka et al. disclose that the barrel additionally comprises a nozzle member 6 (Fig 1), the nozzle is formed in a tip of the nozzle member (as seen in Fig 1), and the nozzle member includes a tip gasket accommodation part 10 (Fig 1) capable of accommodating the tip gasket, and a liquid passing passage 11 (Fig 1) through which a liquid medicine can pass when the tip gasket has been accommodated in the tip gasket accommodation part (Para 49).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (PG PUB 2004/0236273) in view of Higashikawa (US Pat 5,830,193).

11. Re claims 3 and 4, Tanaka et al. disclose that the bypass communication passage includes a circumferential groove formed in an approximately circumferential direction of a base end side of the seal part (as seen in Fig 9) but does not disclose a

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connection passage connecting the groove and the rear chamber. Higashikawa, however, teaches a gasket 104 (Fig 13) having a bypass communication passage that includes a circumferential groove 105₁ (Fig 13) formed in an approximately circumferential direction of a base end side of a seal part 109₁ (Fig 13) and a connection passage 108 (Fig 13) connecting the circumferential groove and the rear chamber (Col 10, Lines 8-15), wherein the connection passage is a groove formed in an outer wall of the intermediate gasket (as seen in Fig 13) for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8-15). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al. to include a connection passage, as taught by Higashikawa, for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8-15).

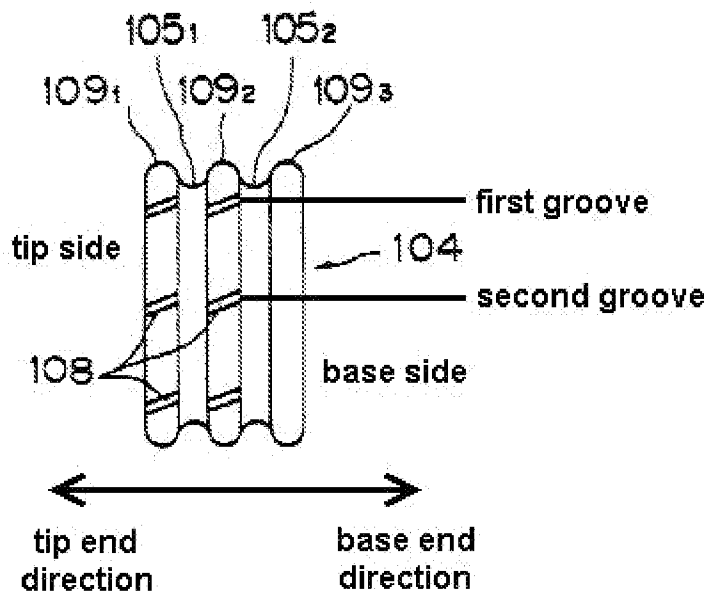
12. Re claim 7, Tanaka et al. disclose all the claimed features except first and second grooves extending in the direction of the base side and tip side. Higashikawa, however, teach that the bypass communication passage comprises a first groove (best seen in Fig B below) extending from an intermediate gasket tip side in a base end direction and at least one second groove (best seen in Fig B below) extending from an intermediate gasket base end side in a tip direction, and a tip of the second groove is located in a tip side relative to a base end of the first groove (best seen in Fig B below) for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8-15). Therefore, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to modify Tanaka et al. to include first and second grooves extending in the direction of the base side and tip side, as taught by Higashikawa, for the purpose of communicating components housed in initially separated chambers with one another (Col 10, Lines 8-15).

Fig B

(annotated Fig 13 of Higashikawa)



13. Re claim 9 (as it is believed to be intended to be written), Tanaka et al. disclose all the claimed features except that the combined length of three gaskets is greater than the length from a nozzle member to an base end of the bypass. Higashikawa, however, teaches that if an axial length of a tip gasket 26 (Fig 9) parallel to the axis of the barrel is A, an axial length of an intermediate gasket 34 (Fig 9) parallel to the axis of the barrel is B, an axial length of a plunger gasket 25 (Fig 9) parallel to the axis of the barrel is C and a length from an inner wall tip of a nozzle member 22 (Fig 9) to an inner wall base end

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of a bypass 24c (Fig 9) is $D, A + B + C > D$ for the purpose of mixing of all components housed in initially separated chambers with one another (Col 8, Lines 33-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al. to include three gaskets whose combined length is greater than the distance between a nozzle member and a base end of a bypass, as taught by Higashikawa, for the purpose of mixing of all components housed in initially separated chambers with one another (Col 8, Lines 33-50).

14. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (PG PUB 2004/0236273)/Higashikawa (US Pat 5,830,193) in view of Grimard et al. (US Pat 5,899,881).

15. Re claim 5, Tanaka et al./Higashikawa disclose all the claimed features except that the grooves are spiral. Grimard et al., however, teach a substantially similar gasket 200 (Fig 1,2) comprising a connection passage 238 (Fig 2) in the form of a spiral groove formed in an outer wall of the gasket (as seen in Fig 2; Col 10, Line 30) for the purpose of fully reconstituting components initially separated from one another (Col 10, Lines 25-32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al./Higashikawa to include spiral grooves, as taught by Grimard et al., for the purpose of fully reconstituting components initially separated from one another (Col 10, Lines 25-32).

16. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (PG PUB 2004/0236273)/Higashikawa (US Pat 5,830,193) in view of Schwartz (US Pat 3,566,859).

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17. Re claim 6, Tanaka et al./Higashikawa disclose all the claimed features except that the connection passage is a conduit formed inside the intermediate gasket.

Schwartz, however, teach a gasket 156 (Fig 11) comprising a connection passage 162 (Fig 11) in the form of a conduit formed inside the gasket (as seen in Fig 11) for the purpose of fluidly connecting portions of a device that would otherwise be unconnected (Col 5, Lines 44-58). Therefore, it would have obvious to one of ordinary skill in the art at the time the invention was made to modify Tanaka et al./Higashikawa to include a conduit, as taught by Schwartz, for the purpose of fluidly connecting portions of a device that would otherwise be unconnected (Col 5, Lines 44-58).

18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al. (PG PUB 2004/0236273)/Higashikawa (US Pat 5,830,193) in view of Bachynsky (US Pat 5,971,953).

19. Re claim 8, Higashikawa disclose a length of the shortest portion within a length of the seal part in the circumferential direction which is separated by the first groove and the second groove (as seen in Fig B above). But Tanaka et al./Higashikawa do not disclose that the circumferential length of the bypass is greater than that circumferential length between the grooves. Bachynsky, however, teaches that a bypass 25 (Fig 2) that extends 360 degrees in a circumferential direction (as seen in Fig 2) for the purpose of allowing fluids in initially separated chambers to mix (Col 7, Lines 24-28). Therefore, if the bypass of Bachynsky were to be combined with the grooves of Higashikawa, then the circumferential length of the bypass would be greater than the length of the shortest portion within a length of the seal part in the circumferential

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direction which is separated by the first groove and the second groove as taught by Higashikawa. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Higashikawa to include a bypass than extends 360 degrees in a circumferential direction, as taught by Bachynsky, for the purpose of allowing fluids in initially separated chambers to mix (Col 7, Lines 24-28).

Response to Arguments

20. Applicant's arguments with respect to claims 1 and 3-11 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAMI A. BOSWORTH whose telephone number is (571)270-5414. The examiner can normally be reached on Monday - Thursday, 7:00 am to 4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. A. B./

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767